

U-CLIP™ Devices, Models B140, B160 &amp; B180

## 510(k) SUMMARY of Safety and Effectiveness

### I. Applicant Information:

Date Prepared: November 18, 2005  
Submitter: Medtronic, Inc.  
  
Address: 710 Medtronic Parkway, NE  
Minneapolis, MN 55432-5604  
  
Establishment  
Registration No. 2135394  
  
Contact Person: David D. Cox, Ph.D.  
Senior Principal Regulatory Affairs Specialist  
  
Telephone Number: (763) 391-9251  
Fax Number: (763) 391-9279

### II. Device Information:

Trade Name: U-CLIP™  
Common Name: Implantable clip

Classification Name: Clip, Implantable  
Classification: Class II, 21 CFR 878.4300  
Product Code: FZP

Predicate Device: Coalescent Surgical U-CLIP™  
510(k) No. K024366, Reg. No. 878.4300; Product Code: FZP

Device Intended Use: The Surgical U-CLIP™ is intended for endoscopic and non-endoscopic general soft tissue and prosthetic material approximation/attachment and/or ligation and the creation of anastomosis in blood vessels, grafts and other tubular structures; including cardiovascular and coronary artery bypass grafting procedures.

## U-CLIP™ Devices, Models B140, B160 &amp; B180

- Device Description:** The U-CLIP™ device is a self-closing clip for anastomosis and tissue and prosthetic material approximation or attachment applications. The U-CLIP™ consists of a self-closing Nitinol clip connected to surgical needles via flexible members. These U-CLIPs™ include a Nitinol wire coil surrounding the Nitinol wire core. This design allows precise placement of clips prior to closure, and facilitates an interrupted "suture" technique by eliminating knot tying. The device is manufactured from a standard implantable grade of Nitinol.
- Intended Use:** The U-CLIP™ Device is intended for endoscopic and non-endoscopic general soft tissue and prosthetic material approximation/attachment and/or ligation and the creation of anastomosis in blood vessels, grafts and other tubular structures.
- Contraindications:** Do not use for tubal ligation.
- Comparison to Predicate Device(s):** The Medtronic U-CLIP™ devices are substantially equivalent to the Coalescent Surgical U-CLIP™ K031623, K024366, K023125, K021407, K013664, K012317, K994160, and K971588 in terms of materials, use and application. The new sizes are a line extension of larger sized clips.
- Test Data:** Verification and validation testing confirms that functional characteristics are substantially equivalent to the predicate device cited. This included clip strength and tissue drag forces. All test data obtained satisfied the documented product and performance specifications.
- Summary:** Based upon the technical information, intended use, *in vitro*, *in vivo*, and clinical performance information provided in previous pre-market notifications, the U-CLIPs™ included in this submission have been shown to be substantially equivalent to currently marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 16 2005

Mr. David D. Cox, Ph.D.  
Senior Principal Regulatory Affairs Specialist  
Medtronic – Cardiac Surgery  
7601 Northland Drive  
Brooklyn Park, Minnesota 55423-1088

Re: K053252  
Trade/Device Name: U-Clip Device, Models B140, B160 and B180  
Regulation Number: 21 CFR 878.4300  
Regulation Name: Implantable Clip  
Regulatory Class: II  
Product Code: FZP  
Dated: November 18, 2005  
Received: November 21, 2005

Dear Dr. Cox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

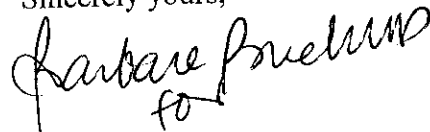
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Dr. Cox

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

Device Name: **U-CLIP**

Indications for Use:

**The U-CLIP™ Device is intended for endoscopic and non-endoscopic general soft tissue and prosthetic material approximation/attachment and/or ligation and the creation of anastomosis in blood vessels, grafts and other tubular structures.**

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K053252